

INTERFERENCE DIGEST

Interference No. 105,619

Paper No.

Name: David J. Pinsky et al.

Serial No.: 10/679,135

Patent No.

Title: Methods for treating ischemic disorders using carbon monoxide

Filed: 10/03/03

Interference with Bach et al.

DECISION ON MOTIONS

Administrative Patent Judge, _____ Dated, _____

FINAL DECISION

Board of Patent Appeals and Interferences, _____ Dated, _____

Court, _____ Dated, _____

REMARKS

This should be placed in each application or patent involved in interference in addition to the interference letters.



UNITED STATES PATENT AND TRADEMARK OFFICE

DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES
BOX INTERFERENCE, WASHINGTON, D.C. 20231

Filed by: Judge Fred E. McKelvey
Telephone: 571-272-4683
Facsimile: 571-273-0042

Applicants: PINSKY
Application No.: 10/679,135
Filed: 10/03/03
For: Methods for treating ischemic disorders using
carbon monoxide

The above-identified application or patent has been forwarded to the Board of Patent Appeals and Interferences because it is adjudged to interfere with another application or patent. An interference has been declared. The interference is designated as No. 105,619.

Notice is hereby given the parties of the requirement of the law for filing in the Patent and Trademark Office a copy of any agreement "in connection with or in contemplation of the termination of the interference." 35 U.S.C. § 135(c).

/Fred E. McKelvey/
FRED E. McKELVEY
Senior Administrative Patent Judge

BoxInterferences@uspto.gov
Telephone: 571-272-4683

Paper 1
Entered: 25 March 2008

UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Patent Interference 105,619 McK
Technology Center 1600

FRITZ H. BACH, LEO E. OTTERBEIN,
MIGUEL P. SOARES and JEANNE GOSE,

Patent 7,238,469 B2,
Junior Party,

v.

DAVID J. PINSKY, DAVID M. STERN
and CHARLES J. PRESTIGIACOME,

Application 10/679,135,
Senior Party,

DECLARATION

1 **Part A**
2 **Declaration of Interference**
3

4 An interference is declared between the above-identified parties.
5 35 U.S.C. § 135(a); 37 CFR § 41.203(b).

6 Details of the application, patent, counts and claims designated as
7 corresponding or as not corresponding to the counts appear in Parts E and F
8 of this DECLARATION.

9
10 **Part B**
11 **Judge Managing the Interference**
12

13 Senior Administrative Patent Judge Fred E. McKelvey has been
14 designated to manage the interference. 37 CFR § 41.104(a).

15
16 **Part C**
17 **Standing Order**
18

19 A Trial Division STANDING ORDER (3 Jan. 2006) (Paper 2)
20 accompanies this DECLARATION.

21 The STANDING ORDER applies to this interference, including the
22 provisions related to Electronic Filing. See ¶ 105, pages 17-20.

23 **Part D**
24 **Initial Conference Call and Motions Lists**
25

26 Conference Call

27 A conference call to discuss the interference is set for:

28 **3:00 p.m. (1500 hours EDT) on 14 May 2008.**

29 The Board will initiate the conference call.
30

Motions Lists

On or before:

Noon (1200 hours EDT) on 09 May 2008,

each party shall file, and on or before:

5:00 p.m. (1700 hours EDT) on 09 May 2008,

each party shall serve a notice stating the relief the party requests, *i.e.*, a motions list including motions the party seeks authorization to file. 37 CFR § 41.120(a); STANDING ORDER ¶ 204 (Paper 2, page 58).

The default procedure for filing and serving motions lists is that motions lists are to be *filed* before being *served*.

By filing before service, one party will not have access to an opponent's motions list prior to the filing of the party's motions list.

Nevertheless, the parties may mutually agree to discuss and serve motions lists at any time prior to the date and time motions lists are due.

The following shall be included in motions lists.

(1) Proposed motion for benefit (*i.e.*, to be accorded an earlier constructive reduction to practice) must identify the application(s) for which benefit will be sought.

(2) Proposed motion to attack benefit must identify the application(s) to be attacked.

(3) Proposed motion seeking judgment against an opponent based on alleged unpatentability must identify the statutory basis for the alleged unpatentability and:

(a) if based on prior art, identify the prior art;

(b) if based on the first paragraph of 35 U.S.C. § 112,

(i) identify whether written description, enablement or best mode will be the

1 basis for the motion, and (ii) briefly identify the basis for any alleged
2 unpatentability;

3 (c) if based on an alleged failure to comply with
4 35 U.S.C. § 135(b), briefly identify the reason;

5 (d) if based on the second paragraph of 35 U.S.C.
6 § 112, identify the limitation which is believed to be indefinite.

7 (4) Proposed motion based on no interference-in-fact shall
8 briefly identify the reason no interference-in-fact is believed to exist.

9 (5) Proposed motion to designate additional claims as
10 corresponding to a count or as not corresponding to a count shall identify the
11 claims involved.

12 (6) Proposed motion to add or substitute a new count shall
13 explain why the added or substitute count is necessary.

14 A motions list shall not contain any "reservation clause" whereby a
15 party purports to reserve a right to file additional motions. Additional
16 motions are those authorized by the Board consistent with the rules.

17 A sample schedule for taking action during the motions phase of the
18 interference appears as Form 2 (page 69) of the STANDING ORDER.

19 Counsel are encouraged to discuss the schedule prior to the
20 conference and agree to on times for taking action generally consistent with
21 the sample schedule.

22 A typical motions phase last about eight (8) months.

23 The parties should be prepared at the conference to justify any request
24 for shorter or longer time periods.

25

1 **Part E**

2
3 **Identification of the Parties**
4 **Assignment of Exhibit Numbers**
5 **Initiating Settlement Discussions**
6

7 Junior Party

8
9 Inventors: Fritz H. Bach, MA
10 Leo E. Otterbein, PA
11 Miguel P. Soares, MA
12 Jeanne Gose, MA
13
14 Patent: U.S. Patent 7,238,469 B2
15 issued 03 July 2007
16 based on application 10/177,930,
17 filed 21 June 2002
18
19 Title: Carbon monoxide improves outcomes in tissue
20 and organ transplants and suppresses apoptosis
21
22 Real party in interest: Beth Israel Deaconess Medical Center, Inc., and
23 Yale University
24

25 Senior Party

26
27 Inventors: David J. Pinsky, MI
28 David M. Stern, GA
29 Charles J. Prestigiacome, NJ
30
31 Application: Application 10/679,135,
32 filed 03 October 2003
33
34 Title: Methods for treating ischemic disorders using
35 carbon monoxide
36
37 Real party in interest: The Trustees of Columbia University in the
38 City of New York
39

1 Assignment of Exhibit Numbers

2 Senior party: Exhibit Numbers 1001 through 1999.

3 Junior party: Exhibit Numbers 2001-2999.

4 Board: Exhibit Numbers 3001-3999.

5 Initiating Settlement Discussions

6 STANDING ORDER ¶ 126.1 (Paper 2, pages 40-41)

7
8
9 The senior party is responsible for initiating settlement discussions
10 required by the STANDING ORDER.

11 **Part F**

12 **Counts and Claims of the Parties**

13 Count 1¹

14
15 A method of transplanting a liver, the method comprising:

16 (a) administering to a donor by inhalation a gaseous
17 pharmaceutical composition comprising about 0.0000001% to about 0.3%²
18 carbon monoxide;

¹ The footnotes are not part of the count.

² The "about 0.0000001% to about 0.3%" comes from U.S. Patent 7,238,469 B2, col. 11:55.

1 (b) obtaining from the donor a liver;³ and
2 (c) transplanting the liver into a recipient, wherein (1) the
3 amount of carbon monoxide administered to the donor in step (a) is
4 sufficient to enhance survival or function of the liver after transplantation
5 into the recipient or (2) the amount and period of time carbon monoxide is
6 administered is sufficient to protectively treat the subject.⁴

³ The organs set out in Counts 1-3 are limited to those explicitly claimed by both parties. See claim 1 of Bach U.S. Patent 7,238,469 B2 and claim 65 of Pinsky application 10/679,135. In addition, it is not apparent from the prior art how the use of the method for a liver would render unpatentable under 35 U.S.C. § 103 use of the method for a heart or pancreas or vice versa. Accordingly, there are three counts. *Cf. Godfredsen v. Banner*, 598 F.2d 589, 592, 202 USPQ 7, 10 (CCPA 1979): "Where, as here, the parties both disclose the same three species, that fact does not justify including those species in a single count as members of a Markush group if the Examiner has determined that the three species are patentably distinct inventions. If such a count were permitted, then the party who proved the earliest date of invention as to any one of the members of the group would be awarded priority as to the entire count, i.e., as to all three members. It is not considered that such a result would be consonant with the primary purpose of an interference or within the intent of 35 U.S.C. § 135, since there would be no determination of priority as to *each* of the common [patentably distinct] inventions claimed by the parties [emphasis in original]."

⁴ Claim 1 of Bach U.S. Patent 7,238,469 B2 uses the language "sufficient to enhance survival or function". Claim 46 of Pinsky application uses the language "sufficient to protectively treat the subject". The (1) and (2) limitations in step (c) of the count are alternative limitations, one based on the language of the Bach patent and the other based on the language of the Pinsky application. Priority proofs must fall within the scope of the count. See 37 C.F.R. § 41.201 (definition of "count"), codifying holdings in cases such as *Squires v. Corbett*, 560 F.2d 424, 433 (CCPA 1977) (count is merely a vehicle for contesting priority and determines what evidence is relevant on the issue of priority). In view of "indefiniteness" concerns discussed in *Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 85 USPQ2d 1654 (Fed. Cir. 2008), the parties are advised that the "sufficient to enhance"

1 The claims of the parties are:

2
3 Bach: 1-54

4
5 Pinsky: 46, 49-51, 53, 56-62, 65 and 89

6
7 The claims that correspond to Count 1 are:

8
9 Bach: 1-14, 20-36 and 49-54

10
11 Pinsky: 46, 49-51, 53, 56-62, 65 and 89

12
13 The claims that do not correspond to Count 1 are:

14
15 Bach: 15-19 and 37-48

16
17 Pinsky: None

18
19 As to Count 1, the parties are accorded an earlier constructive
20 reduction to practice (*i.e.*, benefit for the purpose of priority) of the
21 following applications:

22 Bach: None

23
24 Pinsky: Application 09/671,100
25 filed 27 September 2000

26
27 International application PCT/US99/07175,
28 filed 01 April 1999

and "sufficient to protectively" language gives the Board pause. The parties will be expected to educate the Board on why the language is sufficiently clear to permit proofs on priority and in particular the meanings of "enhance" and "protectively".

Count 2

A method of transplanting a heart, the method comprising:

(a) administering to a donor by inhalation a gaseous pharmaceutical composition comprising about 0.0000001% to about 0.3% carbon monoxide;

(b) obtaining from the donor a heart; and

(c) transplanting the heart into a recipient, wherein (1) the amount of carbon monoxide administered to the donor in step (a) is sufficient to enhance survival or function of the heart after transplantation into the recipient or (2) the amount and period of time carbon monoxide is administered is sufficient to protectively treat the subject.

The claims of the parties are:

Bach: 1-54

Pinsky: 46, 49-51, 53, 56-62, 65 and 89

The claims that correspond to Count 2 are:

Bach: 1-13, 16, 20-33, 40-42 and 49-54

Pinsky: 46, 49-51, 53, 56-62, 65 and 89

The claims that do not correspond to Count 2 are:

Bach: 14-15, 17-19, 34-39 and 43-48

Pinsky: None

1 As to Count 2, the parties are accorded an earlier constructive
2 reduction to practice (*i.e.*, benefit for the purpose of priority) of the
3 following applications:

4 Bach: None

5
6 Pinsky: Application 09/671,100
7 filed 27 September 2000
8

9 Count 3

10 A method of transplanting a pancreas, the method comprising:

11 (a) administering to a donor by inhalation a gaseous
12 pharmaceutical composition comprising about 0.0000001% to about 0.3%
13 carbon monoxide;

14 (b) obtaining from the donor a pancreas; and

15 (c) transplanting the pancreas into a recipient, wherein
16 (1) the amount of carbon monoxide administered to the donor in step (a) is
17 sufficient to enhance survival or function of the pancreas after
18 transplantation into the recipient or (2) the amount and period of time carbon
19 monoxide is administered is sufficient to protectively treat the subject.

20
21 The claims of the parties are:

22
23 Bach: 1-54

24
25 Pinsky: 46, 49-51, 53, 56-62, 65 and 89
26

27 The claims that correspond to Count 3 are:

28
29 Bach: 1-13, 17, 20-33, 43-45 and 49-54

30
31 Pinsky: 46, 49-51, 53, 56-62, 65 and 89
32

1 The claims that do not correspond to Count 3 are:

2
3 Bach: 14-16, 18-19, 34-42 and 46-48

4
5 Pinsky: None

6
7 As to Count 3, the parties are accorded an earlier constructive
8 reduction to practice (*i.e.*, benefit for the purpose of priority) of the
9 following applications:

10 Bach: None

11
12 Pinsky: Application 09/671,100
13 filed 27 September 2000

14

Part G
Heading to be Used on Papers

The following heading shall be used on all papers filed in this
interference [STANDING ORDER ¶ 106.11 (Paper 2, page 20)].

Filed by: [name of party] Paper _____
[Name of attorney] Date filed: [enter date emailed to Board]
[Email address of attorney]
[Telephone number of attorney]

UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Patent Interference 105,619 McK
Technology Center 1600

FRITZ H. BACH, LEO E. OTTERBEIN,
MIGUEL P. SOARES and JEANNE GOSE,

Patent 7,238,469 B2,
Junior Party,

v.

DAVID J. PINSKY, DAVID M. STERN
and CHARLES J. PRESTIGIACOME,

Application 10/679,135,
Senior Party,

Title of Paper, *e.g.*, BACH SUBSTANTIVE MOTION 1

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Part H
Order Form for Requesting File Copies

When requesting file copies, a party shall use STANDING ORDER Form 4 (page 71).

Use of form 4 will expedite processing of any request.

a party should attach to any request for file copies a photocopy of Part E of this DECLARATION with a hand-drawn circle around the patent and application files for which a copy of a file wrapper is requested.

The parties are advised that a single order for file copies may be filled by the Office of Public Records at more than one time. STANDING ORDER ¶ 109.2 (Paper 2, pages 25-27).

Part I
Required Paragraph of Affidavits and Declarations

The Board has experienced cases in which a witness has belatedly advanced reasons why the witness would be unable to appear for cross examination at a reasonable time and place in the United States.

Consequently, to prevent surprise and hardship to the party relying on the testimony of a witness, the following paragraph must be included on the signature page of all affidavits (including declarations) filed in this case.

STANDING ORDER ¶ 157.2 (Paper 2, pages 52-53).

In signing affidavit (declaration), I understand that the affidavit (declaration) will be filed as evidence in a contested case before the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office. I also acknowledge that I may be subject to cross examination in the case and that cross

1 examination will take place within the United States. If cross
2 examination is required of me, I will appear for cross
3 examination within the United States during the time allotted
4 for cross examination.
5
6
7
8

9 /ss/ Fred E. McKelvey)
10 FRED E. McKELVEY)
11 *Senior Administrative Patent Judge*)
12
13

14 Entered at:
15
16 Kailua, HI
17 25 March 2008

1 cc (via Federal Express):
2
3 Attorney for Bach
4 (real party in interest
5 Beth Israel Deaconess Medical Center, Inc., and Yale University):
6
7 Janis K. Fraser, Esq.
8 FISH & RICHARDSON P.C.
9 225 Franklin Street
10 Boston, MA 02110
11
12 Tel: 617-542-5070
13 Fax: None
14 Email: None
15
16
17 Attorney for Pinsky
18 (real party in interest
19 The Trustees of Columbia University in the City of New York):
20
21 John P. White, Esq.
22 COOPER & DUNHAM LLP
23 1185 Avenue of the Americas
24 New York, NY 10036
25
26 Tel: 212-278-0400 (main)
27 Tel: 212-278-0421 (White)
28 Fax: None
29 Email: None
30
31